Before the
Federal Communications Commission
WASHINGTON, D.C. 20554

In the Matter of	)	
	)	
Investigation of the Spectrum Requirements for Advanced Medical Technologies	)	ET Docket No. 06-135
	)	
	)	
Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz	)	RM-11271

MEMORANDUM OPINION AND ORDER

Adopted: July 15, 2010 **Released: July 26, 2010**

By the Commission:

I. INTRODUCTION

1. By this Memorandum Opinion and Order, we address a petition for reconsideration (petition) filed by Medtronic, Inc. (Medtronic) regarding the recently adopted rules for the Medical Device Radiocommunication (MedRadio) service.[1]

2. We grant reconsideration to the extent of amending the MedRadio rules to permit the submission of average power transmitter measurements, and making editorial corrections or clarifications to several provisions concerning the frequency monitoring criteria and permissible communications for "listen-before-talk" (LBT) and non-LBT devices. We deny reconsideration in all other respects and otherwise affirm certain provisions of the MedRadio rules questioned by Medtronic. Our decisions on these issues are discussed below.

II. BACKGROUND

3. The Commission established the MedRadio service under Part 95 of the Rules by *Report and Order* (*MedRadio Order*) in the above-captioned proceeding.[2] Altogether, the MedRadio service provides a total of five megahertz of contiguous spectrum for advanced wireless medical

[1] *See Petition for Reconsideration*, ET Docket No. 06-135, filed June 15, 2009 (petition). Part 95 governs the Personal Radio Services, including General Mobile Radio Service, Radio Control Service and Citizens Band (CB) Radio Service. The CB Radio Service, in turn, covers a number of specialized services, including the MedRadio Service. As with the legacy MICS, MedRadio service devices operate on a secondary, non-interference basis with respect to primary authorized services and, as such, they must accept harmful interference from devices operated under such services. Further, MedRadio devices operate on a shared, non-exclusive basis with respect to each other and other secondary devices.

[2] *See* "Investigation of the Spectrum Requirements for Advanced Medical Technologies Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz," ET Docket No. 06-135, RM-11271, FCC 09-23, *Report and Order*, released March 20, 2009, 24 FCC Rcd 3474; *see also,* "Investigation of the Spectrum Requirements for Advanced Medical Technologies Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz," ET Docket No. 06-135; RM-11271,DA 09-857, *Erratum*, released April 17, 2009, 24 FCC Rcd 4689.

radiocommunication devices serving a diverse range of diagnostic and therapeutic purposes in humans. In the *MedRadio Order*, the Commission also adopted service and technical rules governing the operation of medical radiocommunication devices used in the MedRadio service. Building upon the former Medical Implant Communications Service (MICS) – which limited operation to implanted medical devices – the more flexible MedRadio rules accommodate body-worn as well as implanted medical devices, including those using either LBT or non-LBT spectrum access methods. The MedRadio service incorporates the MICS 'core' band at 402-405 MHz – which continues to be limited to implanted devices – and also includes two megahertz of newly designated spectrum in the adjacent 'wing' bands at 401-402 MHz and 405-406 MHz – in which both body-worn and implanted devices are permitted. The MedRadio service continues to incorporate many of the licensing and technical requirements that applied to the legacy MICS.

III. DISCUSSION

4. In its petition, Medtronic seeks reconsideration of the *MedRadio Order* in four areas. First, Medtronic requests that the MedRadio rules be amended to permit transmitter power measurements to be made using average power instrumentation techniques that were formerly allowed under the MICS rules. For non-LBT devices, it also requests clarification or correction of certain clerical oversights in the rule provisions involving frequency monitoring criteria and permissible communications. For LBT devices, Medtronic requests that we clarify or modify certain provisions of the frequency monitoring rules regarding the transmit power level threshold and the number of channels to be monitored. Finally, Medtronic requests that we reinstate a provision for a particular human torso simulator and testing technique used for measuring radiated emissions and effective isotropic radiated power (EIRP) of implanted devices.

5. *Transmitter Power Measurement*. The former MICS rules stated that compliance with the maximum transmitter power limits shall be based upon measurements using a peak detector function or, alternatively, the instrumentation techniques set forth in a particular American National Standards Institute (ANSI) standard referenced in the rule.[3] That standard has been modified by ANSI since adoption of the MICS rules in 1999[4] and no longer includes the specific average power instrumentation techniques cited by Medtronic. As adopted in the *MedRadio Order*, the new rules set forth a compliance requirement in terms of a "Commission-approved peak power technique."[5]

6. Medtronic requests that the new MedRadio rules be modified to reinstate a provision of the former MICS rules to permit transmitter power compliance measurements using either the peak detector function technique or the substance of the average power instrumentation techniques set forth in the former ANSI standard. Medtronic argues that the Commission did not propose to delete these provisions of the MICS rules in the *Notice of Proposed Rulemaking* (*MedRadio Notice*) that preceded the adoption of the MedRadio rules.[6] Medtronic further asserts that the peak power requirement as set forth in the rule

[3] Former MICS rule section 47 C.F.R. § 95.639(f)(1) (2008) stated: "[. . .] Compliance is based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, instrumentation techniques set forth in ANSI C63.17-1998, Section 6.1.2.2.1 or Section 6.1.2.2.2 may be used in determining compliance with [the applicable limits]."

[4] *See* "Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band," WT Docket No. 99-66, RM-9157, *Report and Order*, 14 FCC Rcd 21040 (1999) (*MICS Order*). 47 C.F.R. Part 95, Subpart I (Medical Implant Communications), and Subpart E (Technical Regulations).

[5] *See* 47 C.F.R. § 95.628(g).

[6] *See* "Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405- (continued….)

adopted in the *MedRadio Order* would, in effect, prohibit the use of average power instrumentation techniques that were acceptable within the scope of the former MICS rule. It contends that the inability to rely upon these average power techniques for compliance would require MedRadio devices to reduce power, and that this, in turn, would be detrimental to the reliable operation of existing equipment and adversely affect the development of new generation devices.[7] To remedy this concern, Medtronic recommends that we reinstate the former MICS rule provision or, in the alternative, restore the intent of the prior rule by substituting text that would permit the use of average power measurement techniques.[8] St. Jude Medical agrees with Medtronic, stating that the effect of the peak power measurement rule will be to sharply reduce the range available to some systems.[9] Biotronik opposes Medtronic's request, stating that the peak power approach adopted in the *MedRadio Order* is a more appropriate technique for MedRadio transmitters because average power measurements would allow higher power devices in the band and, thus, increase the potential for interference in the band.[10]

7. As a threshold matter, we address Medtronic's suggestion that we failed to provide sufficient notice for modifying the power measurement provisions. While we acknowledge that the *MedRadio Notice* did not explicitly request comment on whether the power measurement provisions should be modified, changes to these measurement provisions are a logical outgrowth of issues in the *MedRadio Notice* that we did present for comment. More specifically, the Commission specifically invited comment on power and duty cycle thresholds for MedRadio devices.[11] The *MedRadio Notice* also emphasized that its proposed rules were intended to allow flexibility in spectrum usage for MedRadio devices.[12] When the Commission invited comment on power rules for MedRadio devices, it would be reasonable for interested parties to anticipate that the Commission would also adopt rules for determining whether such devices comply with those rules, including power measurement methods. In addition, in the *MedRadio Notice*, the Commission sought comment on "whether the various current MICS rules would continue to be appropriate for operations under the new allocation."[13] Parties should have anticipated that the Commission could conclude that a reference to an outdated ANSI standard would not "continue to be appropriate for operations under the new allocation." Accordingly, we conclude that the power measurement rule revisions we adopt in this Order are logical outgrowths of the *MedRadio Notice*, and therefore, that the Commission provided sufficient APA notice for these revisions.[14]

(Continued from previous page)
406 MHz, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules," ET Docket No. 06-135, RM-11271, *Notice of Proposed Rulemaking and Notice of Inquiry and Order,* (*MedRadio Notice*) 21 FCC Rcd 8164 (2006).

[7] *See* Medtronic petition at 3.

[8] Medtronic recommends that the third through fifth sentences in new Section 95.628(g)(3) be replaced with the following text: "Average power measurements for transmissions by stations authorized under this section may be used to show compliance with the maximum transmit power limit. Transmit power must be measured over any interval of continuous transmission using instrumentation calibrated in terms of an rms-equivalent voltage." *See* Medtronic petition at 4.

[9] *See* St. Jude Medical reply comment (August 21, 2009) at 2.

[10] *See* Biotronik reply comment (August 11, 2009) at 5. Biotronik asserts that use of average power may allow some devices with 3-5 dB more power, possibly increasing interference in the MedRadio band.

[11] *Med Radio Notice*, 21 FCC Rcd at 8173-74 (para. 25).

[12] *Id*. at 8175 (para. 29).

[13] *Id*. at 8171-72 (para. 20).

[14] *See*, *e.g*. *Public Service Commission of the District of Columbia v. FCC*, 906 F2d 713, 717 (D.C. Cir. 1990) (stating that "it is well established that the exact result reached after a notice and comment rulemaking need not be set out in the initial notice for the notice to be sufficient. Rather, the final rule must be 'a logical outgrowth' of the (continued….)

8. In crafting the new MedRadio rules, the Commission opted to consolidate the transmitter compliance measurement provisions formerly set forth in MICS rule Section 95.639 by creating a new rule Section 95.628(g)(3). As noted above, the new rule deviates from the old rule in that it specifies that power measurements be made using only peak power techniques.[15] At the same time, the Commission also deleted the reference in the old rule to certain measurement techniques set forth in an obsolete ANSI standard – as well as a reference to an alternative technique using a "peak detector function" over a period of time.[16] This language was sufficiently broad to permit the use of an average power measurement technique using the peak detector function. Based on the comments received concerning the removal of this language, we believe that some confusion has been caused over what techniques for measuring transmitter power are allowable under the new rules versus the old rules. At the outset, we note that it was not our intent to change the underlying frame of reference for measuring allowable transmit power, which is a maximum EIRP over a specified bandwidth.[17] Nevertheless, we also recognize that removing the reference to the obsolete ANSI standard (in combination with the reference to the alternative power measurement technique using a peak detector function) contributed to the uncertainty over whether a previously acceptable average power measurement technique would continue to be allowed.

9. Accordingly, we are amending Section 95.628(g)(3) of the MedRadio rules to restore the approach in the former MICS rule which specified a peak detector function as one measurement technique for demonstrating compliance with transmitter power limits.[18] In substitution for the obsolete ANSI standard of the former MICS rule, we are also adding a provision that expands the available options for demonstrating compliance by stating that measurement procedures found acceptable to the Commission in accordance with Section 2.947 may also be used.[19] In addition, the Office of Engineering and Technology (OET) Laboratory Division has published information in its Knowledge Data Base (KDB) concerning acceptable average power measurement procedures under this provision.[20] We believe that this approach satisfies the substance of Medtronic's request that the MedRadio rules be modified to

(Continued from previous page)
rule proposed"); *Small Refiner Lead Phase-Down Task Force v. E.P.A.*, 705 F. 2d 506, 543 (D.C. Cir. 1983) (stating that "under the APA, the final rule must be a "logical outgrowth" of the agency's proposal"); *Health Insurance Association of America, Inc., v. Shalala*, 23 F.3d 412, 421 (D.C. Cir. 1994) (holding that adequate notice is provided if "the final rule is a "logical outgrowth" of the proposals on which the public had the opportunity to comment"). The focus of the "logical outgrowth" test is whether the party should have anticipated that such a requirement might be imposed. *Aeronautical Radio, Inc., v. FCC*, 928 F.2d 428, 445-46 (D.C. Cir. 1991).

[15] "Power measurements for transmissions by stations authorized under this section may be made either in accordance with a Commission-approved peak power technique, or the following. Peak transmit power must be measured over any interval of continuous transmission using instrumentation calibrated in terms of an rms-equivalent voltage. The measurement results shall be properly adjusted for any instrument limitations, such as detector response times, limited resolution bandwidth capability when compared to the emission bandwidth, sensitivity, etc., so as to obtain a true peak measurement for the emission in question over the full bandwidth of the channel." *See* 47 C.F.R. § 95.628(g)(3).

[16] *See* n.3 *supra*.

[17] *See* 47 C.F.R. § 95.639 (f).

[18] *See Appendix A,* § 95.628(g)(3). The relevant amended language states " . . . Compliance with the maximum transmitter power requirements set forth in § 95.639(f) shall be based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, measurement procedures that have been found to be acceptable to the Commission in accordance with Section § 2.947 may be used to demonstrate compliance."

[19] *See id.*

[20] *See* "FCC Guidance for Measuring the Output Power of Transmitting Devices Operating within the Medical Device Radiocommunication Service." Publication Number: 771134. *Available at* https://fjallfoss.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?switch=P&id=44167

permit the average power instrumentation techniques formerly acceptable under the MICS rules.[21]

10. This approach also provides greater flexibility than the former MICS rule, which, in part, relied upon the ANSI standards, because it avoids inadvertent rule obsolescence as industry standards are modified or new measurement techniques are developed. Under the Part 2 rules, specific guidance as to the measurement approaches that are acceptable can readily be provided by the Commission in a more responsive and timely manner through the issuance of bulletins or reports – such as recently has been provided in the OET KDB noted above - and without the need to correct outdated references in the underlying rules through time-consuming, formal proceedings.[22] Moreover, in the event the Commission has not provided guidance on a particular matter through bulletins or reports, the rules also allow parties to provide a detailed description of the measurement procedures actually used for the Commission's consideration in determining compliance with its technical rules.[23]

11. *Non-LBT devices*. Regarding the frequency monitoring criteria for non-LBT devices, Medtronic correctly points out in its petition that the text of the *MedRadio Order* limits the number of transmissions per hour for non-LBT devices, but that these restrictions were omitted from the appropriate subsections of Section 95.628 ("MedRadio Transmitters") as adopted.[24] Medtronic requests that these limitations be added to subsections (b)(2) through (b)(4) – the subsections which also specify the duty cycle limits for non-LBT devices. We concur. The text of the *MedRadio Order* explicitly states that maximum number of communication sessions per hour for non-LBT devices shall be ten (10) per hour for devices operating with 0.01% duty cycle within the 402-405 MHz core band, and one hundred (100) per hour for devices operating with 0.1% duty cycle in the wing bands.[25] The omission of these provisions from the adopted rule was an editorial oversight. We thus amend Section 95.628, subsections (b)(2) through (b)(4) to add these limits, as set forth in Appendix A, to conform to the literal intent of the *MedRadio Order*.

12. Also, Medtronic states that Section 95.1209(d) ("Permissible Communications") as adopted appears to contain unnecessary language that could be interpreted as allowing non-LBT devices to operate without the communication of data.[26] Medtronic argues that such non-data transmissions are inappropriate for non-LBT devices which do not employ frequency monitoring pursuant to Section 95.628(b).[27] Biotronik also supports this request for the same reasons.[28] In the same subsection, Medtronic points out a clerical error in the text which mismatches the cross-references to limits set forth in Section 95.628, subsections (b)(3) through (b)(4), with respect to non-LBT devices operating with 0.1% or 0.01% duty cycles.[29]

13. We agree that the rules should be changed as Medtronic requests. The reference to non-LBT

[21] *See* Medtronic petition at 4.

[22] *See* 47 C.F.R.§ 2.947 (a)(1).

[23] *See* 47 C.F.R. § 2.947 (c).

[24] *See* Medtronic petition at 11.

[25] *See MedRadio Order* at ¶¶ 58-60. We note that non-LBT device are not required to perform frequency monitoring; however, the duty cycle provisions for non-LBT devices are set forth in the rule which is titled "Exceptions to frequency monitoring criteria." *See* 47 C.F.R. § 95.268(b).

[26] *See* Medtronic petition at 12.

[27] In contrast, transmissions without the communication of data are necessary (as part of the session initiation process) for operation of LBT devices that are required to employ frequency monitoring pursuant to §95.628(a).

[28] *See* Biotronik reply comment (August 11, 2009) at 4.

[29] *See* Medtronic petition at 12.

devices operating "without the communication of data" in Section 95.1209(d) as adopted in the *MedRadio Order* was inadvertently carried over from the legacy MICS rule provisions. Historically, MICS devices were limited to LBT operation. Further, as Medtronic correctly points out, some small amount of non-data transmission is necessary to perform the LBT frequency monitoring protocol prescribed in the rules. By comparison, the new MedRadio rules encompass the operation of non-LBT as well as LBT devices. Since non-LBT devices, by definition, do not employ frequency monitoring prior to transmitting data, it would be spectrally inefficient and contrary to the intent of the *MedRadio Order* for such devices to operate without the transmission of data.

14. We thus amend Section 95.1209(d) as set forth in Appendix A to remove the reference to non-LBT devices operating without the communication of data. In addition, we rectify the cross references to the appropriate duty cycle and maximum transmission limits set forth in Section 95.628, – namely, that non-LBT devices operating pursuant to §95.628, subsections (b)(2) and (b)(3), with 0.1% duty cycle may transmit for no more than 3.6 seconds per hour; and that non-LBT devices operating pursuant to Section 95.628, subsection (b)(4), with 0.01% duty cycle may transmit for no more than 360 milliseconds per hour.

15. *LBT Devices*. The frequency monitoring rules for LBT devices require that the devices monitor channel(s) that they intend to occupy but not initiate a communications session unless certain access criteria are met.[30] These criteria include a threshold power level;[31] the LBT device may use a channel if no signal above the threshold power level is detected on that channel or, if no monitored channel meets this requirement, the channel with the lowest ambient power level (the "least-interfered-channel" or "LIC").[32] Medtronic urges the Commission to amend the MedRadio rules to clarify that single-channel LBT devices operating under the LIC provisions of Section 95.628(a)(4) must wait to transmit until the monitoring threshold power level specified in Section 95.628(a)(1) is not exceeded on the device's single channel of operation.[33] Medtronic states its belief that this interpretation was intended by the *MedRadio Order*, but nevertheless seeks clarification to resolve any ambiguity. More specifically, Medtronic observes that the rule's language tacitly envisions MedRadio transmitters capable of operating on multiple channels – such that the availability of an alternate channel is a meaningful option. In this light, Medtronic argues that a strained reading as applied to single channel LBT devices – which, by definition, cannot operate on an alternate channel – could lead to the interpretation that such devices may transmit at will regardless of whether the LBT monitoring threshold had been met. Such an interpretation, Medtronic argues, would essentially write the LBT requirement out of the rule for single channel devices. Biotronik supports this request.[34]

16. We agree that the rules should be amended to state this clarification. The intended interpretation is that the LBT threshold requirement applies to both multi- and single- channel devices. We also concur with Medtronic's assertion that a contrary interpretation would obviate the LBT requirement for single channel devices, thereby undermining our goal of fostering equitable band sharing by all LBT devices. Further, while we believe that the contrary characterization that Medtronic cautions against would be a strained reading of the rule, we nevertheless wish to prevent any misunderstanding. Accordingly, as applied to single channel LBT devices, we clarify that Section 95.628(a)(4) shall be interpreted to require that such devices must wait to transmit until the monitoring threshold on the single

[30] *See* 47 C.F.R.§ 95.628 (a).

[31] *See* 47 C.F.R. § 95.628 (a)(1).

[32] *See* 47 C.F.R. § 95.628 (a)(4).

[33] *See* Medtronic petition at 9.

[34] *See* Biotronik reply comment (August 11, 2009) at 4.

channel of operation is not exceeded.[35] We are adding text to Section 95.628(a)(4) reflecting this clarification.

17. Medtronic also requests that we clarify that a MedRadio device operating under the LIC provisions of Section 95.628(a)(4) must monitor – and be capable of operating on – a specified minimum number of channels (*e.g.*, 9 for the core band, and 18 for the wing bands).[36] With support from Biotronik, Medtronic argues that such a requirement would ensure that devices using the least interfered channel provisions of Section 95.628(a)(4) operate on the remaining alternate channels that have the lowest ambient power levels, thereby fostering more efficient band sharing while minimizing mutual interference.

18. We decline to modify the rule and affirm the rule as adopted. As an initial matter, we note that no such requirement was contained in the former MICS rules, and that no mention of adopting such a requirement was made in the *MedRadio Notice*. Furthermore, and on the merits, we also find that establishing such a requirement on reconsideration would be inconsistent with our general desire, as articulated in the *MedRadio Order,* to adopt rules generally in conformance with the MICS while providing greater flexibility. We believe that it is desirable to give manufacturers and the marketplace ample opportunity to determine the device channeling capabilities that are most useful for a particular application. Thus far, no problems have been reported to us resulting from this flexibility, and Medtronic presents no facts that would cause us to reconsider this decision.

19. Finally, Medtronic asks that we reconsider the decision in the *MedRadio Order* to reject Medtronic's request – which it first raised in a January 10, 2008 *ex parte* submission – to modify the LBT monitoring threshold set forth in Section 95.628 (a)(3) for devices that transmit with less than the maximum allowed power.[37] The Commission declined to modify the LBT monitoring threshold because the issue was not raised in the *MedRadio Notice* and thus there was little substantive basis on the record for modifying the rule.[38] At the time of its submission, Medtronic asked that the "listen-before-talk" (LBT) threshold specified in the MICS rules be modified to increase the LBT threshold by 1 db for every 1 dB that the EIRP of the monitoring systems transmitter is below the maximum permitted level of 25 microwatts EIRP for both body-worn and implanted MedRadio devices across the entire 401-406 MHz MedRadio band.[39] Medtronic further stated that this modification would harmonize with recently adopted ETSI standards for low-power medical device data communications in other countries.[40] Medtronic merely reiterates these claims in its petition, and suggests that the requested modification would only affect devices with lower interference potential.[41] More recently, in subsequent *ex parte* submissions, Medtronic characterizes its request as being limited to body-worn devices when acting as programmer/control transmitters, and that it is not seeking a change to the LBT threshold for standalone programmer/control transmitters.[42]

20. Upon reconsideration, we affirm the finding in the *MedRadio Order* that insufficient notice

[35] Non-LBT devices, on the other hand, may nevertheless transmit on a channel when the monitoring threshold is not met provided that they meet the frequency monitoring exceptions for such non-LBT operation set forth in § 95.628(b).

[36] *See* Medtronic petition at 9-10.

[37] *See* Medtronic petition at 7.

[38] *See MedRadio R&O* at ¶ 55, n.76.

[39] *See* Medtronic *Ex Parte Letter* (January 10, 2008) at 1.

[40] *See id*.

[41] *See id*.

[42] *See* Medtronic *Ex Parte Letter* (August, 21, 2009) at 7; Medtronic *Ex Parte Letter* (January 29, 2010) at 2.

was provided in the *MedRadio Notice* to support modifying the LBT threshold as requested. The mere fact that Medtronic raised the subject of a modified LBT threshold for the first time in an *ex parte* submission does not cure this basic lack of sufficient notice in the *MedRadio Notice* itself.[43]

21. We also affirm the finding in the *MedRadio Order* that there was insufficient substantive discussion in the comment record to support such a modification.[44] We believe that modifying the monitoring threshold as suggested by Medtronic raises several issues that require further analysis. For example, Medtronic states that this modification would harmonize with recently adopted ETSI standards for low-power medical device data communications in other countries, but seeks to limit its application to only body-worn devices when acting as programmer/control transmitters across the entire 401-406 MHz MedRadio band.[45] Although the ETSI standard cited by Medtronic does include the substance of the modified LBT threshold, this standard only covers the 401-402 MHz and 405-406 MHz wing bands, and also applies to both implanted and body-worn devices when used to select the frequency of operation.[46] In addition, we have to consider the impact of a higher monitoring threshold on primary METAIDS users in these frequency bands which might increase the likelihood of a medical device seeking to operate on a channel being used by a METAIDS device. Medtronic seeks to minimize these concerns by asserting that LBT medical devices would suffer no more interference from METAIDS devices than non-LBT devices, but it offers no analysis to support this assertion.[47] These concerns lead us to conclude that insufficient substantive record has been developed to act on Medtronic's request at this time.[48] The first step to develop such a record, to the extent it wishes to further proceed on this question, is for Medtronic to file a petition for rulemaking with the Commission.

22. *Human Torso Simulator and Testing Technique*. The transmitters used for medical implant and body-worn devices authorized under the MedRadio rules are required to be tested to determine compliance with radiated emissions and EIRP limits.[49] Medtronic requests that the rules be modified to reinstate a provision requiring use of a particular human torso simulator test technique for implanted

[43] Medtronic points to several locations in the *MedRadio Notice* to support its argument that notice was provided, but we believe that Medtronic is taking these references to the monitoring threshold out of context. The *MedRadio Notice* sought comment on allowing non-LBT devices in the core and wing bands, which would obviate the need for a monitoring threshold, but at power levels much lower than those proposed for LBT devices.

[44] *See MedRadio R&O* at ¶ 55, n.76.

[45] *See id*. at 1 and appendix.

[46] *See* "Electromagnetic Compatibility and Radio Spectrum Matters (ERM);Short Range Devices (SRD);Ultra Low Power Medical Data Service Systems Operating in the Frequency Range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical Characteristics and Test Methods" ETSI EN 302 537-1 V1.1.2 (2007-12) (Section 10.2, pps 32 *et seq*)

[47] *See* Medtronic *Ex Parte Letter* (January 29, 2010) at 7. Likewise, Medtronic asserts that LBT devices operating at less than allowed power would not cause interference to METAIDS devices, citing IU-R RS 1346, *Sharing Between The Meteorological Aids Service and Medical Implant Communication Systems (MICS) Operating In The Mobile Service In The Frequency Band 401-406 MHz*, but this document does not address the issue quantitatively but instead makes broad assertions.

[48] For example, is it feasible or practical from a manufacturing perspective to have different LBT thresholds apply to body-worn and standalone programmer/control transmitters as Medtronic requests? What would the impact be of having two different LBT thresholds for different devices in the band have on the overall risk of interference between MedRadio devices, as well as to and from METAIDS operations? How can the dual LBT threshold approach suggested by Medtronic be reconciled with the ETSI standard which appears to relax the LBT threshold for both implanted and body-worn devices when used to select the operating channel? If such a modified LBT threshold were to be adopted, should it apply across the entire 401-406 MHz band, or just the 403-405 MHz core band, or the remaining wing bands?

[49] *See* 47 C.F.R. § 95.628 (g).

medical devices that was set forth in former Section 95.639(f)(2)(i) of the MICS rules.[50] Medtronic states that the corresponding new MedRadio provision, Section 95.628(g)(3)(i), which more broadly requires a "Commission-approved human body simulator and test technique," fails to provide sufficient guidance about what type of measurement data is required. Medtronic also claims that no changes to the test technique were proposed in the *MedRadio Notice*.[51] Medtronic further argues that the former MICS provision reduces possible confusion by providing, in effect, a safe harbor for compliance purposes. Biotronik supports this request for the same reasons.

23. We are denying this request and affirming Section 95.628(g)(3)(i) of the new MedRadio rules as adopted. The new rule is more permissive than the former MICS rule and provides greater flexibility in testing devices by expanding, rather than limiting, available measurement compliance options. As we observed above regarding procedures for measuring average power, Section 2.947 of the rules allows the Commission to provide specific guidance as to the measurement approaches that would be acceptable in a more responsive and timely manner through the issuance of bulletins or reports and without the need to correct outdated references in the underlying rules through time-consuming, formal proceedings. Moreover, in the event the Commission has not provided guidance through bulletins or reports, the rules also allow parties to provide a detailed description of the measurement procedures actually used for the Commission's consideration in determining compliance with its technical rules. This approach also forestalls inadvertent rule obsolescence as new measurement techniques are developed. More to the point with respect to Medtronic's concerns herein, we affirm that the new rules do not preclude use of the "human torso" simulator described in the former MICS rules. Finally, as with the transmitter power measurement issue discussed above, we note that the OET Laboratory Division has published information in its KDB concerning acceptable measurement procedures under this provision, including a statement that use of the human torso technique formerly codified in the MICS rules continues to be acceptable.[52]

IV. PROCEDURAL MATTERS

A. Final Regulatory Flexibility Analysis

24. Consistent with the Regulatory Flexibility Act, *see* 5 U.S.C. § 604, the Commission has prepared a Final Regulatory Flexibility Analysis (RFA) of the possible significant economic impact on small entities of the rules amended in this document. The FRFA is set forth in Appendix B.

B. Paperwork Reduction Analysis

25. This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506(c)(4).

C. Congressional Review Act

26. The Commission will send a copy of this Memorandum Opinion and Order, in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A),

[50] *See* Medtronic petition at 5.

[51] *Id*.

[52] *See* "Human Torso Simulator and Testing Technique." Publication Number: 617965. *Available at* https://fjallfoss.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?switch=P&id=44325

D. Contact Persons

27. For further information concerning this rule making proceeding contact: Gary Thayer at (202) 418-2290, Gary.Thayer@fcc.gov; Office of Engineering and Technology.

V. ORDERING CLAUSES

28. Accordingly, IT IS ORDERED that, pursuant to the authority contained in Sections 4(i), 302, 303(e), 303(f), and 307 of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 302, 303(c), 303(f), and 307 this Memorandum Opinion and Order IS HEREBY ADOPTED.

29. IT IS FURTHER ORDERED that Part 95 of the Commission's rules IS AMENDED as specified in Appendix A, and such rule amendments shall be effective 30 days after publication in the Federal Register

30. IT IS FURTHER ORDERED that, pursuant to Sections 4(i), 302, 303(e) 303(f), 303(g), 303(r) and 405 of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), 302, 303(e), 303(f), 303(g) and 405, that the petition for reconsideration filed by Medtronic, Inc. IS GRANTED IN PART and DENIED IN PART as set forth above.

31. IT IS FURTHER ORDERED, that the Commission’s Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this *Memorandum Opinion and Order*, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

32. IT IS FURTHER ORDERED that ET Docket No. 06-135 IS TERMINATED.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch
Secretary

APPENDIX A

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 C.F.R. Part 95 to read as follows:

PART 95 – PERSONAL RADIO SERVICES

1. The authority citation for part 95 continues to read as follows:

AUTHORITY: Sections 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303

2. Section 95.628 is amended by revising paragraphs (a), (b) and (g) to read as follows:

§ 95.628 MedRadio Transmitters.

* * * * *

(a) *Frequency Monitoring*. Except as provided in (b) below, all MedRadio programmer/control transmitters operating in the 401-406 MHz band must operate under the control of a monitoring system that incorporates a mechanism for monitoring the channel or channels that the MedRadio system devices intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before the monitoring system of a MedRadio programmer/control transmitter initiates a MedRadio communications session, the following access criteria must be met:

(1) * * *

(2) * * *

(3) * * *

(4) If no signal in a MedRadio channel above the monitoring threshold power level is detected, the MedRadio programmer/control transmitter may initiate a MedRadio communications session involving transmissions to and from a medical implant or medical body-worn device on that channel. The MedRadio communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in paragraph (a)(3) of this section is unavailable, MedRadio transmitters that are capable of operating on multiple channels may transmit on the alternate channel accessible by the device with the lowest monitored ambient power level. Except as provided in subpart (b) of this section, MedRadio transmitters that operate on a single channel and thus do not have the capability of operating on alternate channels may not transmit unless no signal on the single channel of operation exceeds the monitoring threshold power level.

(5) * * *

(6) * * *

(b) *Exceptions to frequency monitoring criteria*. MedRadio devices or communications sessions that meet any one of the following criteria are not required to use the access criteria set forth in paragraph (a) of this section:

(1) * * *

(2) MedRadio devices operating in either the 401-401.85 MHz or 405-406 MHz bands, provided that the transmit power is not greater than 250 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval, and a maximum of 100 transmissions per hour.

(3) MedRadio devices operating in the 401.85-402 MHz band, provided that the transmit power is not greater than 25 microwatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one hour interval, and a maximum of 100 transmissions per hour.

(4) MedRadio devices operating with a total emission bandwidth not exceeding 300 kHz centered at 403.65 MHz, provided that the transmit power is not greater than 100 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.01%, based on the total transmission time during a one-hour interval, and a maximum of 10 transmissions per hour.

(c) * * *

(d) * * *

(e) * * *

(f) * * *

(g) *Measurement Procedures.*

(1) * * *

(2) * * *

(3) Radiated emissions and EIRP measurements may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Compliance with the maximum transmitter power requirements set forth in § 95.639(f) shall be based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, measurement procedures that have been found to be acceptable to the Commission in accordance with Section § 2.947 may be used to demonstrate compliance.

(i) * * *

(ii) * * *

* * * * *

3. Section 95.1209 is amended by revising paragraph (d) to read as follows:

§ 95.1209 Permissible communications.

* * * * *

(d) For the purpose of facilitating MedRadio system operation during a MedRadio communications session, as defined in § 95.628, MedRadio transmitters may transmit in accordance with the provisions of § 95.628(a) for no more than 5 seconds without the communications of data; MedRadio transmitters may transmit in accordance with the provisions of § 95.628(b)(2) & (b)(3) for no more than 3.6 seconds in total within a one hour time period; and MedRadio transmitters may transmit in accordance with the provisions of § 95.628(b)(4) for no more than 360 milliseconds in total within a one hour time period.

APPENDIX B

Final Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice of Proposed Rulemaking* (*MedRadio NPRM*) in this proceeding.[2] The Commission sought written public comment on the proposals in the *MedRadio NPRM*, including comment on the IRFA. In addition, a Final Regulatory Flexibility Analysis (FRFA) was incorporated in the subsequent *Report and Order* (*MedRadio Order*) in this same proceeding.[3] This Final Regulatory Flexibility Analysis (FRFA) for the subject Memorandum Opinion and Order conforms to the RFA.[4]

A. Need for and Objective of Adopted Rules.

The subject Memorandum Opinion and Order responds to the Petition for Reconsideration submitted by Medtronic, Inc. on June 15, 2009.[5] It grants reconsideration to the extent of including a provision in the MedRadio rules that permits the submission of transmitter output power measurements made using average power instrumentation techniques. It also makes several minor corrections or clarifications of an editorial nature with respect to other provisions. It denies reconsideration in all other respects.

The need for and objectives of the amended rules adopted in this Memorandum Opinion and Order are the same as those discussed in the FRFA for the Report and *MedRadio Order*. In the *MedRadio Order*, the Commission found that additional spectrum was required for the operation of advanced medical devices using wireless telecommunication technologies. Thus, building upon the legacy Medical Implant Communications Service (MICS), the Commission adopted service and technical rules for a new MedRadio Service that replicated, and expanded upon, many of the former MICS requirements. For example, the legacy MICS rules limited operation to implanted medical devices. However, the rules for the new MedRadio Service adopted in the *MedRadio Order* accommodate body-worn as well as implanted medical devices. Under this framework, the rules for MedRadio service incorporates the MICS 'core' band at 402-405 MHz – which continues to be limited to implanted devices; and also includes two megahertz of newly designated spectrum in the adjacent 'wing' bands at 401-402 MHz and 405-406 MHz – in which both body-worn and implanted devices are permitted. As with the MICS, the MedRadio

[1] *See* 5 U.S.C. § 603. The RFA, *see* 5 U.S.C. §§ 601-612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. No. 104-121, Title II, 110 Stat. 857 (1996).

[2] *See* Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz, Dexcom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 06-135, RM-11271, *Notice of Proposed Rule Making and Notice of Inquiry and Order, (MedRadio Notice)* 21 FCC Rcd 8164 (2006).

[3] *See* Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz, Dexcom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 06-135, RM-11271, *Report and Order*, (*MedRadio Report and Order*) 24 FCC Rcd 22696 (2009).

[4] *See* 5 U.S.C. § 604.

[5] See *Petition for Reconsideration*, ET Docket No. 06-135, filed by Medtronic on June 15, 2009.

service is housed within Part 95 of the Commission's rules.[6] As a result, the legacy MICS and new MedRadio rules share many of the same licensing and technical requirements. Altogether, the MedRadio service provides a total of five megahertz of contiguous spectrum for advanced wireless medical radiocommunication devices serving a diverse range of diagnostic and therapeutic purposes in humans.

B. Summary of Significant Issues Raised by Public Comments in Response to the FRFA.

No comments were filed in response to the FRFA in this proceeding. In addition, no comments were submitted concerning small business issues.

C. Description and Estimate of the Number of Small Entities to Which the Adopted Rules Will Apply.

The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.[7] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."[8] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[9] A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[10]

In the FRFA the Commission stated that nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.[11] A "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field."[12] Nationwide, as of 2002, there were approximately 1.6 million small organizations.[13] The term "small governmental jurisdiction" is defined generally as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand."[14] Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.[15] The Commission estimates that, of

[6] Part 95 governs the Personal Radio Services, including General Mobile Radio Service, Radio Control Service and Citizens Band (CB) Radio Service. The CB Radio Service, in turn, covers a number of specialized services, including the MedRadio Service. As with the legacy MICS, the MedRadio service devices operate on a secondary, non-interference basis with respect to primary authorized services and, as such, they must accept harmful interference from devices operated under such services. Further, MedRadio devices operate on a shared, non-exclusive basis with respect to each other and other secondary devices.

[7] 5 U.S.C. § 603(b)(3).

[8] 5 U.S.C. § 601(6).

[9] 5 U.S.C. § 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. § 632). Pursuant to the RFA, the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register." 5 U.S.C. § 601(3).

[10] Small Business Act, 15 U.S.C. § 632 (1996).

[11] *See* SBA, Programs and Services, SBA Pamphlet No. CO-0028, at page 40 (July 2002).

[12] 5 U.S.C. § 601(4).

[13] Independent Sector, The New Nonprofit Almanac & Desk Reference (2002).

[14] 5 U.S.C. § 601(5).

[15] U.S. Census Bureau, Statistical Abstract of the United States: 2006, Section 8, page 272, Table 415.

this total, 84,377 entities were "small governmental jurisdictions."[16] Thus, we estimate that most governmental jurisdictions are small.

Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing. The Census Bureau defines this category as follows: "This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment."[17] The SBA has developed a small business size standard for firms in this category, which is: all such firms having 750 or fewer employees.[18] According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year.[19] Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999.[20] Thus, under this size standard, the majority of firms can be considered small.

D. Description of Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities.

The Memorandum Opinion and Order does not change any of the reporting, recordkeeping, or other compliance requirements resulting from the rules adopted in the *MedRadio Order*. As stated above, the only substantive rule change in the Memorandum Opinion and Order merely reinstates a provision from the former MICS rules that permits the submission of average power transmitter measurements.

Furthermore, as stated in the FRFA, the rules adopted by the Commission in the *MedRadio Order* use the same licensing approach for the entire 401-406 MHz MedRadio band that was previously used for the legacy MICS band at 402-405 MHz. Rather than require individual transmitter licensing, the Commission authorizes operation by rule within the Citizens Band (CB) Radio Service under Part 95 of our Rules and pursuant to Section 307(e) of the Communications Act.[21] Thus, licensing will be

[16] We assume that the villages, school districts, and special districts are small, and total 48,558. *See* U.S. Census Bureau, Statistical Abstract of the United States: 2006, section 8, page 273, Table 417. For 2002, Census Bureau data indicate that the total number of county, municipal, and township governments nationwide was 38,967, of which 35,819 were small. *Id.*

[17] U.S. Census Bureau, 2007 NAICS Definitions, "334220 Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing"; http://www.census.gov/naics/2007/def/ND334220.HTM#N334220..

[18] 13 C.F.R. § 121.201, NAICS code 334220.

[19] U.S. Census Bureau, American FactFinder, 2002 Economic Census, Industry Series, Industry Statistics by Employment Size, NAICS code 334220 (released May 26, 2005); http://factfinder.census.gov. The number of "establishments" is a less helpful indicator of small business prevalence in this context than would be the number of "firms" or "companies," because the latter take into account the concept of common ownership or control. Any single physical location for an entity is an establishment, even though that location may be owned by a different establishment. Thus, the numbers given may reflect inflated numbers of businesses in this category, including the numbers of small businesses. In this category, the Census breaks-out data for firms or companies only to give the total number of such entities for 2002, which was 929.

[20] *Id*. An additional 18 establishments had employment of 1,000 or more.

[21] We note that 47 U.S.C. § 307(e)(3) provides that the term "citizens band radio service" shall have the meaning given it by the Commission by rule. 47 U.S.C. § 307(e)(1) provides that upon determination by the Commission (continued….)

accomplished through adherence to applicable technical standards and other operating rules. The Commission concluded in the *MedRadio Order* that this approach is beneficial because it would minimize the administrative burden on prospective licensees as compared with an individual licensing scheme.

E. Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered.

The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.[22]

In the preceding *MedRadio NPRM*, the Commission sought comment on which regulatory approaches would be appropriate to govern the MedRadio Service. Subsequently, in the *MedRadio Order* the Commission considered the responsive comments filed by interested parties, and determined that record as a whole supported extending the license-by-rule approach under Part 95 - used by the former MICS - to the new MedRadio service because of the reduced regulatory impact on all licensees.

F. Report to Congress.

The Commission will send a copy of the Memorandum Opinion and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act.[23] In addition, the Commission's Consumer and Governmental Affairs Bureau will send a copy of the Memorandum Opinion and Order, including the FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Memorandum Opinion and Order and FRFA (or summaries thereof) will also be published in the Federal Register.[24]

(Continued from previous page)
that an authorization serves the public interest, convenience, and necessity, the Commission may by rule authorize the operation of radio stations without individual licenses in the citizens band radio service.

[22] *See* 5 U.S.C. § 603(c).

[23] *See* 5 U.S.C. § 801(a)(1)(A).

[24] *See* 5 U.S.C. § 604(b).